Subpart D—Guidelines for Effectiveness Testing

§ 350.60 Guidelines for effectiveness testing of antiperspirant drug products.

An antiperspirant in finished dosage form may vary in degree of effectiveness because of minor variations in formulation. To assure the effectiveness of an antiperspirant, the Food and Drug Administration is providing guidelines that manufacturers may use in testing for effectiveness. These guidelines are on file in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. These guidelines are available on the FDA's Web site at http://www.fda.gov/cder/otc/index.htm or on request for a nominal charge by submitting a Freedom of Information (FOI) request in writing to FDA's FOI Staff (HFI–35), 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857.

PART 352—SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE [STAYED INDEFINITELY]

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—Labeling

Subpart D—Testing Procedures

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 64 FR 27687, May 21, 1999, unless otherwise noted.

EFFECTIVE DATE NOTE: At 68 FR 33381, June 4, 2003, part 352 was stayed until further notice, effective June 4, 2004.

Subpart A—General Provisions

§ 352.1 Scope.

(a) An over-the-counter sunscreen drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 352.3 Definitions.

As used in this part:

(a) *Minimal erythema dose (MED).* The quantity of erythema-effective energy (expressed as Joules per square meter) required to produce the first perceptible, redness reaction with clearly defined borders.

(b) *Product category designation (PCD).* A labeling designation for sunscreen drug products to aid in selecting the type of product best suited to an individual's complexion (pigmentation) and desired response to ultraviolet (UV) radiation.

(1) *Minimal sun protection product.* A sunscreen product that provides a sun protection factor (SPF) value of 2 to under 12.

(2) *Moderate sun protection product.* A sunscreen product that provides an SPF value of 12 to under 30.

(3) *High sun protection product.* A sunscreen product that provides an SPF value of 30 or above.

(c) *Sunscreen active ingredient.* An active ingredient listed in § 352.10 that absorbs, reflects, or scatters radiation in the UV range at wavelengths from 290 to 400 nanometers.

(d) *Sun protection factor (SPF) value.* The UV energy required to produce an MED on protected skin divided by the UV energy required to produce an MED on unprotected skin, which may also be defined by the following ratio: SPF